

## FLUID LENS

## RELATED INVENTIONS

This is a continuation in part of U.S. patent application Ser. No. 06/432,409 filed on Sept. 30, 1982, now U.S. Pat. No. 4,466,705.

## BACKGROUND OF THE INVENTION

The present invention relates generally to an improved lens and, more particularly, to an improved lens which utilizes fluid, and particularly to fluid in the form of a hydrated hydrophilic polymer array, as its primary lens medium. The lens according to the present invention is especially suited for use as an intraocular lens.

It has long been recognized that ocular lenses made of glass or substantially rigid plastic result in irritation, discomfort and alteration of the normal corneal physiology. Therefore, attempts have been made to reduce these effects by using softer, more permeable lens materials, particularly in the area of contact lenses. For example, U.S. Pat. No. 2,241,415 to Moulton discloses an ophthalmic lens having a supporting portion formed of a thin, soft, pliable and slightly plastic material.

In recent years, so called "soft" contact lenses have been manufactured which utilize hydrogels as lens materials to reduce eye irritation and discomfort. For example, in U.S. Pat. No. 4,123,408, Gordon discloses a contact lens of a hydrogel composition wherein the hydrogel utilizes a polymerized water-insoluble, water-swellaable polymer composition. U.S. Pat. No. 4,153,349 to Wichterle also discloses a method of making hydrogel contact lenses having improved lens properties. While "soft" contact lenses have reduced irritation and discomfort experienced while using prior art lenses, the soft contact lenses, while softer than prior art rigid lenses, must be sufficiently rigid to maintain the desired lens shape when utilized by the wearer and therefore a significant amount of foreign matter is introduced into the eye.

Any time foreign matter is introduced into the eye, there is a potential problem that irritation and discomfort will result even if the material is relatively soft. It will also hinder the passage of oxygen, nutrients, other gases and metabolites between cornea and tear film and thus potentially alter the normal physiology and clarity of the cornea. The ideal lens would utilize body fluids, such as lachrymal fluids, to form the desired lens and thereby completely eliminate the need for introduction of foreign material into the eye. However, since it is not possible to retain such fluid in a desired lens configuration, at least some type of structural member must be included to form the fluid into the shape of the lens.

Therefore, the use of fluid in connection with ocular devices has been generally relegated to purposes other than the formation of a primary lens medium. For example, U.S. Pat. No. 3,710,796 to Neeffe discloses an ophthalmic dressing where a drug is impregnated into a transparent osmotic permeable material which serves to define the shape of the device. Diffusion of the drug out of its impregnated or dispersed state within this homogeneous polymer apparently determines the drug delivery rate. European Patent Application No. 32,517 published July 29, 1981 discloses a lens which permits the configuration of the device to a cornea by utilizing an insert filled with physiologically compatible fluid such as lachrymal fluid. However, the lens utilizes a soft

contact material, not the fluid, as the primary lens medium.

## SUMMARY OF THE INVENTION

It is an object of the present invention to provide a new and improved lens.

It is a further object of the invention to provide a new and improved lens which utilizes fluid as the primary lens medium.

It is an additional object of the present invention to provide a new and improved lens which utilizes fluid as the primary lens medium and is particularly suited for use as an ocular lens.

It is another object of the present invention to provide a new and improved lens which utilizes fluid as the primary lens medium while keeping the structural material which forms the fluid in the shape of a lens to a minimum.

It is yet another object of the invention to provide a new and improved lens which utilizes fluid in the form of a hydrated, hydrophilic polymer array as the primary lens medium.

It is still a further object of the present invention to provide a new and improved lens which utilizes a semipermeable membrane to maintain a fluid body in a desired lens shape.

It is yet a further object of the present invention to provide a new and improved lens which utilizes a semipermeable membrane to maintain a fluid body in a desired lens shape and which retains the desired shape as a result of a pressure differential existing across the membrane.

It is an additional object of the present invention to provide a new and improved lens which will permit the delivery of physiologically active agents.

It is a further object of the present invention to provide a new and improved lens which will permit the maximum exchange of gases, nutrients and metabolites between cornea, lachrymal fluid and the atmosphere, thus minimally compromising normal physiology.

Another object of the present invention is to provide a physiological lenticule capable of being introduced into the substance of the cornea with minimal disruption of its normal physiology while at the same time, altering significantly its shape and refractive power.

Additional objects and advantages of the present invention will be set forth in part in the description which follows and in part will be obvious from the description or can be learned by practice of the invention. The objects and advantages are achieved by means of the processes, instrumentalities and combinations particularly pointed out in the appended claims.

To achieve the foregoing and other objects and in accordance with its purpose, the present invention provides a device for forming a fluid lens when immersed in a liquid medium. The device includes a semipermeable transparent sheath defining a fully enclosed cavity and having a plurality of pores for permitting a liquid to flow into the cavity. A hydrophilic polymer array is disposed in the cavity and presents a pressure differential across the sheath when the sheath is immersed in the liquid medium for causing liquid medium to flow into the cavity and to hydrate the array, causing the array to expand and to completely fill the cavity, thereby causing the sheath to expand and to assume a defined lenticular shape, wherein the hydrated array assumes a shape having an outer contour defined by the expanded sheath and constitutes a fluid lens.